UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: September 28, 2021

SUBJECT: Amended Efficacy Review for DV 5-26762
EPA Reg. No. 4564-ET
Action Code Case: 00294299; E-sub: 61498

FROM: Tahirah Burford
Efficacy Branch
Antimicrobials Division (7510P)
Date Signed: September 28, 2021

THRU: Thao Pham
Efficacy Branch
Antimicrobials Division (7510P)
Date Signed: November 5, 2021

TO: Joe Daniels / Eric Miederhoff, PM 31
Regulatory Management Branch I
Antimicrobials Division (7510P)

APPLICANT: Solvay USA Inc.
504 Carnegie Center
Princeton, New Jersey 08540

FORMULATION FROM LABEL:

Active Ingredient(s)	% by wt.
Alkyl (C14-50%;C12-40%;C16-10%) Dimethyl Benzyl Ammonium Chloride	0.250%
Didecyl Dimethyl Ammonium Chloride	0.250%
Other ingredients:	99.500%
Total	100.000%

I BACKGROUND

Product Description (as packaged, as applied): RTU Liquid (Spray Application)

Submission type: New Product Registration

Currently registered efficacy claim(s): N/A

Requested action(s): Applicant is submitting efficacy data to support a new product registration, including label claims for disinfectant (bactericidal and virucidal), non-food contact sanitizer, and residual self-sanitizer.

Documents considered in this review:

- Cover letter from applicant to EPA, dated March 15, 2021
- Proposed label, dated June 24, 2021
- Data Matrix (EPA Form 8570-35) dated 03/15/2021
- Efficacy studies (MRIDs 51481610-51481617 & 51481620)
- Confidential Statement of Formula (EPA Form 8670-4) dated 03/10/2021
- Terms of Registration, dated May 3, 2021
- AD Efficacy Review for EPA File Symbol 4564-ET, dated September 7, 2021.

Note: Per the technical screen, MRIDs 51481618 and -19 were not reviewed as these studies do not align with the agency's guidance for supporting a residual disinfection claim.

Documents submitted in response to Agency Pre-Decisional Determination Letter (dated September 8, 2021):

- 4564-ET Supplemental Data with Relative Humidity dated September 09, 2021
- Cover letter from applicant to EPA, dated October 5, 2021
- Data Matrix (EPA Form 8570-35) dated 10/5/21
- Supplemental information to support MRIDs 51481614-6 (MRIDs 51703401-3)
- Terms of Registration, dated September 22, 2021
- Proposed label, dated 09-22-2021

II AGENCY STANDARDS FOR PROPOSED CLAIMS

Agency Standards for Making Viral Emerging Pathogen Claims in accordance with the agency publication *Guidance to Registrants: Process for Making Claims against Emerging Viral Pathogens not on EPA-registered Disinfectant Labels*:

1. The product is an EPA-registered, hospital/healthcare or broad-spectrum disinfectant with directions for use on hard, non-porous surfaces.

2. The currently accepted product label should have disinfectant efficacy claims against at least one of the following viral pathogen groupings**:**

For an emerging viral pathogen that is a/an…	*Qualifying criterion*
Enveloped virus emerging viral pathogen	At least one large OR one small non-enveloped virus
Large, non-enveloped emerging viral pathogen	At least one small, non-enveloped virus
Small, non-enveloped emerging viral pathogen	At least two small, non-enveloped viruses with each from a different viral family

III Proposed Directions for Use

"To Sanitize Hard Non-porous Surfaces:
Remove any visible soil from surface prior to sanitizing. Apply product using a [cloth][sponge][trigger sprayer] to hard non-porous surface until visibly wet. Allow surface to remain visibly wet for 60 seconds. Wipe clean with a [clean cloth][damp cloth][sponge] [paper towel]. [[Kills] [Effective against] [99.9% of] [*{Insert non-food contact sanitization bacteria from **Table B: List of Sanitization Organisms}***]

To Sanitize Hard Non-porous Surfaces for 24 hours:
Remove any visible soil from surface prior to sanitizing. Apply product using a [cloth][sponge][trigger sprayer] to hard non-porous surface until visibly wet. Allow surface to remain visibly wet for 5 minutes. Allow to air dry. [[Kills] [Effective against] [99.9% of] [*{Insert non-food contact sanitization bacteria from **Table B: List of Sanitization Organisms}***]

[Disinfecting] [Directions] {Trigger Spray}
To Disinfect Hard Non-porous Surfaces
[For General Broad Spectrum Non-Food Contact [Bacterial] Disinfection][One Step Cleaner/Disinfectant][For hospital disinfection of bacteria and viruses†]:
Remove any visible soil from surface prior to disinfection. Hold container 6"-8" from surface and spray until visibly wet. Allow surface to remain visibly wet for 5 minutes. [Then wipe with [clean cloth][sponge][paper towel].] [Kills [effective against] [99.9% of] [*{Insert disinfection bacteria from **Table A: List of Disinfection Organisms}***]."

IV. STUDY SUMMARIES

1.	**MRID**	51481610		
Study Title		Standard test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces		
Study Objective		Non Food Contact sanitizer		
Testing Lab; Lab Study ID		Analytical Lab Group-Midwest, Project No. A31152		
Experimental Start Date		10/30/2020	**Study Completion Date:**	02/09/2021
Test organism(s) **☐ 1 ☒ 2 ☐ 3 ☐ 4+**		*Klebsiella aerogenes,* ATCC 13408 *Staphylococcus aureus*, ATCC 6538		
Test Method		American Society for Testing and Materials (ASTM), Standard test method E1153-14; Protocol No. SVY0191720.NFS		
Application Method		RTU Liquid		
Test Substance Preparation	**Name/ID**	DV 5-26762		
	Lots **☐ 1 ☐ 2 ☒ 3**	S1528-205-09D S1528-205-18D S1528-205-27D		
	Preparation	Tested concentration: LCL Tested Dilution: N/A Diluent: N/A		
Soil load		5% FBS soil load was used		
Carrier type, # per lot		Glass 1" x 1" carriers, 5		
Test conditions		Contact time: 60 seconds Temperature: 20°C actual Relative Humidity: 17%		

Neutralizer	D/E Neutralizing Broth + 1.5% Lecithin + 5.0% Tween 80
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)	Protocol Deviations: The protocol states that the TCT control will use 25 mL of sterile diluent and the NTT control will use 25 mL of sterile neutralizer. The protocol modifications section states that 40 mL of neutralizer should be used to ensure proper neutralization. To match the volume of neutralized solution as performed in the test and the NCT controls, 45.0 mL of sterile diluent was used in the TCT control and 45.0m3 of sterile neutralizer was used in the NTT control. This deviation has no impact on the overall intent of the protocol as the volume of solution for the TCT and NTT controls need to match the volume of solution as in the test and NCT controls and for testing performed on 10/30/20, the NC controls passed the acceptance criteria.

2.	**MRID**	51481611		
Study Title		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces		
Study Objective		Disinfectant – virucidal		
Testing Lab; Lab Study ID		Analytical Lab Group-Midwest, Project No. A31547		
Experimental Start Date		12/23/2020	**Study Completion Date:**	02/05/2021
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Human Rotavirus, ATCC-VR 2018, Strain WA		
Indicator Cell Culture		MA-104 (Rhesus monkey kidney) cells (ATCC CRL 2378.1)		
Test Method		American Society for Testing and Materials (ASTM), Standard test method E1053-20; Protocol No. SVY01120420.ROT.1		
Application Method		RTU Liquid		
Test Substance Preparation	**Name/ID**	DV 5-26762		
	Lots **☐ 1 ☒ 2 ☐ 3**	S1528-205-18D S1528-205-27D		
	Preparation	Tested concentration: LCL Tested Dilution: N/A Diluent: N/A		
Soil load		5% FBS soil load was used		
Carrier type, # per lot		Glass 1” x 1” carriers, 1		
Test conditions		Contact time: 5 minutes Temperature: 20°C actual Relative Humidity: 40%		
Neutralizer		Sephadex Gel Filtration Column		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Study report was amended on 2/15/21 to replace Certificates of Analysis for both test lots due to calculation error.		

3.	**MRID**	51481612
Study Title		Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

Study Objective		Disinfectant – virucidal		
Testing Lab; Lab Study ID		Analytical Lab Group-Midwest, Project No. A31548		
Experimental Start Date		12/23/2020	**Study Completion Date:**	02/05/2021
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Human Rotavirus, ATCC-VR 2018, Strain WA		
Indicator Cell Culture		MA-104 (Rhesus monkey kidney) cells (ATCC CRL 2378.1)		
Test Method		American Society for Testing and Materials (ASTM), Standard test method E1053-20; Protocol No. SVY01120420.ROT.2		
Application Method		RTU Liquid		
Test Substance Preparation	**Name/ID**	DV 5-26762		
	Lots **☐ 1 ☒ 2 ☐ 3**	S1528-205-18D S1528-205-27D		
	Preparation	Tested concentration: LCL Tested Dilution: N/A Diluent: N/A		
Soil load		5% FBS soil load was used		
Carrier type, # per lot		Glass 1” x 1” carriers, 1		
Test conditions		Contact time: 10 minutes Temperature: 20°C actual Relative Humidity: 40%		
Neutralizer		Sephadex Gel Filtration Column		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Study report was amended on 2/15/21 to replace Certificates of Analysis for both test lots due to calculation error.		

4.	**MRID**	51481613		
Study Title		Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard Nonporous Surfaces		
Study Objective		Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard Nonporous Surfaces		
Testing Lab; Lab Study ID		Analytical Lab Group-Midwest; Project No. A31480		
Experimental Start Date		12/07/2020	**Study Completion Date:**	03/01/20
Test organism(s) **☐ 1 ☒ 2 ☐ 3 ☐ 4+**		*Klebsiella aerogenes* (ATCC 13048) *Staphylococcus aureus* (ATCC 6538)		
Test Method		Association of Official Analytical Chemists (AOAC) Official Method 960.09, Germicidal and Detergent Sanitizing Action or Disinfectants Method [Preparation of Synthetic Hard Water. In Official Methods of Analysis of the AOAC, 2013 Edition.; Protocol No. SVYO1091620.RES.2		
Application Method		RTU Liquid		
Test Substance Preparation	**Name/ID**	DV5-26762		
	Lots **☐ 1 ☐ 2 ☒ 3**	S1528-205-09D S1528-205-18D S1528-205-27D		
	Preparation	Tested concentration: LCL Tested Dilution: N/A Diluent: N/A		

Soil load	5% fetal bovine serum
Carrier type, # per lot	304 stainless steel surfaces (1" x 1"); 4 test carriers per batch and 4 control carriers
Test conditions	Contact time: 5 minutes Temperature: 19-20°C actual Relative humidity: 20-24%
Neutralizer	TAT Broth
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)	Protocol Amendments: 1. Due to the departure of the original Study Director from Analytical Lab Group, this protocol is amended to change the Study Director from Rick Shimshock to James Walrath. 2. Due to inadvertent omission, this protocol is amended to include Attachment Ill to align this protocol with the February 2018 version of the 810.2000 Product Performance Test Guidelines. This deviation had no impact on the study since the conducted dilution is below that label use dilution. Summary: DV 5-26762 (Lots S1528-205-09D, Lot S1528-205-18D, Lot S1528-205-27D) ready to use was tested against *Klebsiella aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538) following 12 wear cycles, 5 re-inoculations at a 5 minute exposure time when tested at ambient temperature (19-20°C) and 20-24% RH in the presence of a 5% fetal bovine serum organic soil load.

5.	**MRID**	51481614		
Study Title		AOAC 961.02 Germicidal Spray Products as Disinfectants		
Study Objective		Disinfectant – bactericidal		
Testing Lab; Lab Study ID		Accugen Laboratories Inc., Lab #170607, 170609, &170611		
Experimental Start Date		2/15/21	**Study Completion Date:**	3/4/21
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Pseudomonas aeruginosa* ATCC 15442		
Test Method		AOAC 961.02 Germicidal Spray Products as Disinfectants; Protocol #:02062021-sui-bacti		
Application Method		RTU spray using 3 sprays at 7 inches		
Test Substance Preparation	**Name/ID**	DV5-26762		
	Lots **☐ 1 ☐ 2 ☒ 3**	S1528-205-09D S1528-205-18D S1528-205-27D		
	Preparation	Tested concentration: LCL Tested Dilution: N/A Diluent: N/A		
Soil load		5% fetal bovine serum		
Carrier type, # per lot		Microscope Glass Slide Carriers 25 x 25 mm, 60		
Test conditions		Contact time: 5 minutes Temperature: 20±1°C actual Relative Humidity:		

	Lot # S1528-205-09D: 75 % Lot # S1528-205-18D: 76% Lot # S1528-205-27D: 75%
Neutralizer	DE Neutralizing broth
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)	Relative humidity was provided in supplemental document

6.	**MRID**	51481615		
Study Title		AOAC 961.02 Germicidal Spray Products as Disinfectants		
Study Objective		Disinfectant – bactericidal		
Testing Lab; Lab Study ID		Accugen Laboratories Inc., Lab #170604, 170605, & 170606		
Experimental Start Date		2/15/21	**Study Completion Date:**	3/3/21
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Staphylococcus aureus* ATCC 6538		
Test Method		AOAC 961.02 Germicidal Spray Products as Disinfectants; Protocol #:02092021-sui-bacti		
Application Method		RTU spray using 3 sprays at 7 inches		
Test Substance Preparation	**Name/ID**	DV5-26762		
	Lots **☐ 1 ☐ 2 ☒ 3**	S1528-205-09D S1528-205-18D S1528-205-27D		
	Preparation	Tested concentration: LCL Tested Dilution: N/A Diluent: N/A		
Soil load		5% fetal bovine serum		
Carrier type, # per lot		Microscope Glass Slide Carriers 25 x 25 mm, 60		
Test conditions		Contact time: 5 minutes Temperature: 20±1°C actual Relative Humidity: Lot # S1528-205-09D: 75 % Lot # S1528-205-18D: 76% Lot # S1528-205-27D: 76%		
Neutralizer		DE Neutralizing broth		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Relative humidity was provided in supplemental document		

7.	**MRID**	51481616		
Study Title		AOAC 961.02 Germicidal Spray Products as Disinfectants		
Study Objective		Disinfectant – bactericidal		
Testing Lab; Lab Study ID		Accugen Laboratories Inc., Lab #170608, 170610, & 170612		
Experimental Start Date		2/15/21	**Study Completion Date:**	3/4/21
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Salmonella enterica* ATCC 10708		
Test Method		AOAC 961.02 Germicidal Spray Products as Disinfectants;		

		Protocol #:020102021-sui-bacti
Application Method		RTU spray using 3 sprays at 7 inches
Test Substance Preparation	**Name/ID**	DV5-26762
	Lots ☐ **1** ☐ **2** ☒ **3**	S1528-205-09D S1528-205-18D S1528-205-27D
	Preparation	Tested concentration: LCL Tested Dilution: N/A Diluent: N/A
Soil load		5% fetal bovine serum
Carrier type, # per lot		Microscope Glass Slide Carriers 25 x 25 mm, 60
Test conditions		Contact time: 5 minutes Temperature: 20±1°C actual Relative Humidity: Lot # S1528-205-09D: 76 % Lot # S1528-205-18D: 75% Lot # S1528-205-27D: 76%
Neutralizer		DE Neutralizing broth
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Relative humidity was provided in supplemental document

8.	**MRID**	51481617	
Study Title		A GLP Virucidal Efficacy Evaluation of One Hard Non-Porous Surface Disinfectant Substance	
Study Objective		Disinfection-virucidal	
Testing Lab; Lab Study ID		Biosciences Inc.; Project No. 2009681-404A	
Experimental Start Date		11/13/2020	**Study Completion Date:** 12/09/2020
Test organism(s) ☐ **1** ☐ **2** ☒ **3** ☐ **4+**		Influenza A H1N1 Strain A/WS/33 (ATCC VR-1520) Respiratory Syncytial Virus, strain Long (HRSV; ATCC VR-26) Coronavirus strain 229E (ATCC VR-740)	
Indicator cells		Influenza A H1N1: MDCK (ATCC CCL-34) Human Respiratory Syncytial Virus: Hep-2 (ATCC CCL-23) Coronavirus: MRC-5 (ATCC CCL-171)	
Test Method		American Society for Testing and Materials (ASTM), Standard test method E1053-20	
Application Method		RTU Liquid	
Test Substance Preparation	**Name/ID**	DV5-26762	
	Lots ☐ **1** ☒ **2** ☐ **3**	S1528-205-18D S1528-205-27D	
	Preparation	Tested concentration: LCL Tested Dilution: N/A Diluent: N/A	
Soil load		5% fetal bovine serum	
Carrier type, # per lot		304 stainless steel surfaces (1" x 1"); 4 test carriers per batch and 4 control carriers	
Test conditions		**Contact time**: 5 minutes	

	Temperature: Influenza A H1N1: 23.8°C Human Respiratory Syncytial Virus: 23.1-23.4°C Coronavirus strain 229E: 23.4-23.8°C **Relative humidity:** Influenza A H1N1: 10.80% to 11.40% Human Respiratory Syncytial Virus: 14.57% to 15.48% Coronavirus strain 229E: 14.18% to 15.23%
Neutralizer	Dey-Engley (D/E) Neutralizing Broth (BSLI)
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)	Protocol Amendments: The Study Protocol was amended once. The Sponsor requested to exclude SARS-CoV-2 virus strain USA-WA1/2020 (BEI Resources NR52281). In addition, test substance, DV 5-26762, Batch #3 Lot S1528-205-09D was removed from testing as it is not a requirement of ASTM E1053-20 to test three batches of test formulation. The Sponsor also requested two separate Final Reports issued for this study. Final Report #2009681-404A presents the results for Influenza A H1N1 (ATCC VR-1520), Human Respiratory Syncytial Virus (ATCC #VR-26), and Coronavirus 229E (ATCC #VR-740). Final Report #2009681-404B presents the results for Feline Calicivirus (ATCC #VR-782) (not submitted for agency review).

9.	**MRID**	51481620		
Study Objective		Disinfection-virucidal		
Testing Lab; Lab Study ID		Biosciences Inc.; Project No. 2012965-408		
Experimental Start Date		1/25/2021	**Study Completion Date:**	2/23/2021
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		SARS-CoV-2, strain USA-WA1/2020 (BEI Resources # NR-52281)		
Indicator cells		Vero cells (ATCC CRL-1586)		
Test Method		American Society for Testing and Materials (ASTM), Standard test method E1053-20		
Application Method		RTU Liquid		
Test Substance Preparation	**Name/ID**	DV5-26762		
	Lots **☐ 1 ☐ 2 ☒ 3**	S1528-205-09D S1528-205-18D S1528-205-27D		
	Preparation	Tested concentration: LCL Tested Dilution: N/A Diluent: N/A		
Soil load		5% fetal bovine serum		
Carrier type, # per lot		Glass petri dishes (100 mm x 15 mm); 1 carrier per batch		
Test conditions		**Contact time**: 5 minutes **Temperature:** 23.1-23.4°C **Relative humidity:** 23%		
Neutralizer		Dey-Engley (D/E) Neutralizing Broth (BSLI)		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)				

V. STUDY RESULTS

Non-Food Contact Sanitizer on Hard Surface Efficacy

MRID	Organism	Results				Population Control Geometric Mean CFU/ carrier (Average Log_{10})
		Batch #	Average Log_{10} CFU/ carrier	Geometric Mean	Percent Reduction	
60-second contact time, Ready-to-use liquid, 5% FBS soil load						
51481610	*Klebsiella pneumoniae* (ATCC 4352)	S1528-205-09D	< 1.99	< 9.77×10^1	> 99.99%	5.62×10^6 (6.75)
		S1528-205-18D	< 1.65	< 4.47×10^1	> 99.999%	
		S1528-205-27D	< 1.65	< 4.47×10^1	> 99.999%	
51481610	*Staphylococcus aureus* (ATCC 6538)	S1528-205-09D	3.29	< 1.95×10^3	> 99.9%	7.41×10^6 (6.87)
		S1528-205-18D	3.31	< 2.04×10^3	> 99.9%	
		S1528-205-27D	3.83	< 6.76×10^3	> 99.9%	

Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard Nonporous Surfaces

MRID	Organism	Results				Population Control Geometric Mean CFU/ carrier (Average Log_{10})
		Batch #	Average Log_{10} CFU/ carrier	Geometric Mean	Percent Reduction	
5-minute contact time, Ready-to-use liquid, 5% FBS soil load						
51481613	*Klebsiella pneumoniae* (ATCC 4352)	S1528-205-09D	2.56	3.63×10^2	99.9%	1.29×10^6 (6.11)
		S1528-205-18D	2.91	8.13×10^2	99.9%	
		S1528-205-27D	2.35	2.24×10^2	99.9%	
51481613	*Staphylococcus aureus* (ATCC 6538)	S1528-205-09D	< 1.48	< 3.02×10^1	> 99.99%	2.34×10^6 (6.37)
		S1528-205-18D	< 1.88	< 7.59×10^1	> 99.99%	
		S1528-205-27D	< 1.48	< 3.02×10^1	> 99.99%	

Disinfection – Bactericidal Efficacy

MRID	Organism	No. Exhibiting Growth / Total No. Tested			Average log_{10} CFU/Carrier
		Batch #1: S1528-205-09D	**Batch #2: S1528-205-18D**	**Batch #3: S1528-205-27D**	
5-minute contact time, RTU Liquid (Spray Application), 5% FBS soil load					
51481614	*Pseudomonas aeruginosa* (ATCC 15442)	0/60	0/60	0/60	Batch S1528-205-09D: 4.23×10^5
					Batch S1528-205-18D: 4.13×10^5
					Batch S1528-205-27D: 2.16×10^5
51481615	*Staphylococcus aureus* (ATCC 6538)	0/60	0/60	0/60	Batch S1528-205-09D: 3.15×10^6
					Batch S1528-205-18D: 2.9×10^6
					Batch S1528-205-27D: 2.93×10^6
51481616	*Salmonella enterica* (ATCC 10708)	0/60	0/60	0/60	Batch S1528-205-09D: 3.4×10^4
					Batch S1528-205-18D: 3.08×10^5
					Batch: S1528-205-27D 3.42×10^4

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results		Dried Virus Control ($TCID_{50}$/carrier)
			S1528-205-18D	S1528-205-27D	
5-minute contact time, RTU liquid, 5% FBS soil load					
51481611	Human Rotavirus, ATCC-VR 2018, Strain WA	10^{-1} dilution	Cytotoxicity present	Cytotoxicity present	6.55 log_{10}
		10^{-2} to 10^{-8} dilution	Complete inactivation	Complete inactivation	
		$TCID_{50}$/carrier	≤1.80 log_{10}	≤1.80 log_{10}	
		Log Reduction	≥4.75 log_{10}	≥4.75 log_{10}	
51481617	Influenza A H1N1 Strain A/WS/33 (ATCC #VR-1520)	10^{-2} dilution	Cytotoxicity present	Cytotoxicity present	5.55 log_{10}
		10^{-3} dilution	Virus infected cells present	Virus infected cells present	
		10^{-4} dilution	Virus infected cells present	Complete inactivation	
		10^{-5} to 10^{-7} dilution	Complete inactivation	Complete inactivation	
		$TCID_{50}$/carrier	2.55 log_{10}	2.30 log_{10}	
		Log Reduction	3.00 log_{10}	3.25 log_{10}	
51481617	Human Respiratory Syncytial Virus, strain Long (HRSV; ATCC VR-26)	10^{-2} dilution	Cytotoxicity present	Cytotoxicity present	5.05 log_{10}
		10^{-3} to 10^{-7} dilution	Complete inactivation	Complete inactivation	
		$TCID_{50}$/carrier	1.80 log_{10}	1.80 log_{10}	
		Log Reduction	3.25 log_{10}	3.25 log_{10}	
51481617	Coronavirus strain 229E (ATCC VR-740)	10^{-2} dilution	Cytotoxicity present	Cytotoxicity present	5.05 log_{10}
		10^{-3} to 10^{-7} dilution	Complete inactivation	Complete inactivation	
		$TCID_{50}$/carrier	1.80 log_{10}	1.80 log_{10}	
		Log Reduction	3.25 log_{10}	3.25 log_{10}	
10-minute contact time, RTU liquid, 5% FBS soil load					
51481612	Human Rotavirus, ATCC-VR 2018, Strain WA	10^{-1} dilution	Cytotoxicity present	Cytotoxicity present	6.30 log_{10}
		10^{-2} to 10^{-8} dilution	Complete inactivation	Complete inactivation	
		$TCID_{50}$/carrier	≤1.80 log_{10}	≤1.80 log_{10}	
		Log Reduction	≥4.50 log_{10}	≥4.50 log_{10}	

MRID	Organism	Description	Results			Dried Virus Control ($TCID_{50}$/carrier)
			S1528-205-09D	S1528-205-18D	S1528-205-27D	
5-minute contact time, RTU liquid, 5% FBS soil load						
51481620	SARS-Related Coronavirus 2, BEI Resources NR-52281, Strain Isolate USA-WA1/2020	10^{-2} dilution	Complete inactivation	Complete inactivation	Complete inactivation	5.05 log_{10}
		10^{-3} to 10^{-7} dilution	Complete inactivation	Complete inactivation	Complete inactivation	
		$TCID_{50}$/carrier	≤1.80 log_{10}	≤1.80 log_{10}	≤1.80 log_{10}	
		Log Reduction	≥3.25 log_{10}	≥3.25 log_{10}	≥3.25 log_{10}	

VI. STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support label claims?
51481610	Non-Food Contact Sanitizer	Hard non-porous surface	RTU Liquid	60 seconds	5 FBS%	None	*Klebsiella pneumoniae* (ATCC 4352) *Staphylococcus aureus* (ATCC 6538)	• Yes
51481611	Disinfectant, virucidal	Hard non-porous surface	RTU Liquid	5 minutes	5% FBS	None	Human Rotavirus, ATCC-VR 2018, Strain WA	• Yes
51481612	Disinfectant, virucidal	Hard non-porous surface	RTU Liquid	10 minutes	5% FBS	None	Human Rotavirus, ATCC-VR 2018, Strain WA	• Yes
51481613	Residual Self-Sanitizing Activity of Dried Chemical Residues	Hard non-porous surface	RTU Liquid	5 minutes	5% FBS	None	*Klebsiella pneumoniae* (ATCC 4352) *Staphylococcus aureus* (ATCC 6538)	• Yes
51481614	Disinfectant, bactericidal	Hard non-porous surface	RTU Spray	5 minutes	5% FBS	None	*Pseudomonas aeruginosa* (ATCC 15442)	• Yes

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support label claims?
51481615	Disinfectant, bactericidal	Hard non-porous surface	RTU Spray	5 minutes	5% FBS	None	*Staphylococcus aureus* (ATCC 6538)	• Yes
51481616	Disinfectant, bactericidal	Hard non-porous surface	RTU Spray	5 minutes	5% FBS	None	*Salmonella enterica* (ATCC 10708)	• Yes
51481617	Disinfectant, virucidal	Hard non-porous; surface	RTU Liquid	5 minutes	5% FBS	None	Influenza A H1N1 Strain A/WS/33 (ATCC VR-1520) Human Respiratory Syncytial Virus, strain Long (HRSV; ATCC VR-26) Coronavirus strain 229E (ATCC VR-740)	• Yes
51481620	Disinfectant, virucidal	Hard non-porous surface	RTU Liquid	5 minutes	5% FBS	None	SARS-CoV-2, strain USA-WA1/2020 (BEI Resources NR-52281)	• Yes

MRID	Emerging virus claim	Organism(s)	Type of Virus (family)	Surface Type	Application Method(s) and/or Dilution	Contact Time	Soil load	Data support label claims?
51481611	Enveloped Viruses	Human Rotavirus, ATCC-VR 2018, Strain WA	Large, non-enveloped	Hard non-porous surface	Ready-to-Use liquid	5 minutes	5% FBS	Yes

VII. LABEL COMMENTS

Label Date: DV 5-26762, EPA Reg. No. 4564-ET (dated 09-22-2021)

1. The proposed label claims that the product referenced above, when applied as a RTU Liquid, is an effective sanitizer against the following on nonfood contact, hard, non-porous surfaces for a 60-second contact time:

Klebsiella pneumoniae (ATCC 4352)	MRID 51481610
Staphylococcus aureus (ATCC 6538)	MRID 51481610

   These claims are **acceptable** as they are supported by the submitted data.

2. The proposed label claims that the product referenced above, when applied as a RTU Liquid, is an effective residual self-sanitizer for up to 24 hours against the following on nonfood contact, hard, non-porous surfaces for a 5-minute contact time:

Klebsiella pneumoniae (ATCC 4352)	MRID 51481613
Staphylococcus aureus (ATCC 6538)	MRID 51481613

   These claims are **acceptable** as they are supported by the submitted data.

3. The proposed label claims that the product referenced above, when applied as a RTU spray, is an effective disinfectant against the following viruses on hard, non-porous surfaces for a 5-minute contact time:

Human Rotavirus, ATCC-VR 2018, Strain WA	MRID 51481611
Influenza A H1N1 Strain A/WS/33 (ATCC VR-1520)	MRID 51481617
Human Respiratory Syncytial Virus, strain Long (HRSV; ATCC VR-26)	MRID 51481617
Coronavirus strain 229E (ATCC VR-740)	MRID 51481617
SARS-CoV-2, strain USA-WA1/2020 (BEI Resources # NR-52281)	MRID 51481620

   These claims are **acceptable** as they are supported by the submitted data..

4. The proposed label claims that the product referenced above, when applied as a RTU spray, is an effective disinfectant against the following viruses on hard, non-porous surfaces for a 10-minute contact time:

Human Rotavirus, ATCC-VR 2018, Strain WA	MRID 51481612

   This claim is **acceptable** as it is supported by the submitted data..

5. The proposed label claims that the product referenced above, when applied as a RTU spray, is an effective disinfectant against the following bacteria on hard, non-porous surfaces for a 5-minute contact time:

Pseudomonas aeruginosa (ATCC 15442)	MRID 51481614
Staphylococcus aureus (ATCC 6538)	MRID 51481615
Salmonella enterica (ATCC 10708)	MRID 51481616

   These claims are **acceptable** as they are supported by the submitted data.

6. The proposed label claims that the product, DV 5-26762, qualifies for the following emerging viral pathogens claims as described in the letter from the applicant to EPA dated September 22, 2021:

For an emerging viral pathogen that is a/an…	*…follow the directions for use for the following organisms on the label:*
Enveloped virus	Human Rotavirus, ATCC-VR 2018, Strain WA

These claims are **acceptable** as they are supported by the submitted data.

7. Make the following changes to the proposed label:

a. Throughout the label,
   i. ensure one-step pesticidal claims are linked to the appropriate use directions (e.g. "when used according to disinfection directions".
   ii. ensure pesticidal and non-pesticidal marketing claims are distinct for clarity and efficacy (e.g. "[antibacterial][antimicrobial] all-purpose cleaner"

b. On page 6, "multi-action cleaning power" appears multiple times. Recommend that "multi-action" be future described to ensure the claims is limited to cleaning and overly broad or implying activity beyond cleaning.

c. On page 7,
   i. remove or revise "[the cleaner that] provides… sanitization…", "multi-surface cleaner [with][and][&] [24 hour sanitizing]" and "Multi-purpose cleaner [with][and][&] [24 hour sanitizing]" as the label has separate instructions for cleaning vs. sanitizing and combining these in marketing claims may be confusing and misleading.
   ii. For "Helps you [protect][defend][guard] your treated hard non-porous surfaces from bacteria", add "for 24 hours"

d. On page 8,
   i. remove '>' symbol in "eliminates >99.9%" as this could imply up to 100% kill. remove brackets around "[99.9%]" when this appears after "eliminates" as the percent kill is not optional. 'Eliminates' may imply up to complete kill without the percentage specification. "antibacterial cleaner" or revise to specify the appropriate use directions, since cleaning is not pesticidal.

e. On page 9,
   i. Remove brackets from around "99.9% of" in the claim, "Eliminates tough stains and [99.9% of] bacteria and viruses†" (Note: there is strike-through formatting on the brackets, but they still exist on the clean label)
   ii. Each instance of 'Kills…SARS-CoV 2' should be linked with "on hard nonporous surfaces". This text should not be bracketed as optional for this virus

f. On page 11, specify "non porous" for 'coated mattresses' and 'coated pillows'.

g. On page 12, remove brackets from "[Exterior]" for toilets and urinals.